Cahoy Dec.
Ex. 91

Brandon Hansen

From: Yen, Dwight <Dwight.Yen@fda.hhs.gov>
Sent: Tuesday, August 27, 2013 5:15 AM
To: Brandon Hansen
Cc: Domecus Consulting; Nipper, Joshua
Subject: IS4000 K131861
Attachments: K131861-emc fax.doc; K131861- clinical fax.doc; K131861-sterility-biocomp fax.doc; K131861-bench fax.doc; K131861-Software fax.doc; K131861- hf fax.doc

Follow Up Flag: Follow up
Flag Status: Flagged

Hello Brandon,

We have completed our initial review on this huge submission. Please find several attachments for deficiency questions on this submission. I have separated our deficiency questions into groups based on feedback from each members of the review team. This constitute our initial significant interaction (SI) and will place this submission on telephone hold to stop the 90 days clock.

I will call you later today to see if you have any quick questions and to discuss strategy going forward with this submission.

Best regards,
Dwight

Date: August 23, 2013
To: Brandon Hansen
From: Dwight Yen

Subject: 510(k) for the da Vinci IS4000 (K131861)

Per my phone message, here are the deficiency questions related to the software:

For all the following information, please provide a table of contents with page numbers and tabbed sections, with each section repeating the question which is being addressed and clearly providing the answers to each of these additional information questions. If some of the information was provided in the original submission, please repeat that information in your response: do not just reference some previously submitted information.

1. Level of Concern
   You concluded that the Level Of Concern (LOC) was MODERATE. The Agency considers this to be a MAJOR LOC device. Please correct your LOC.

2. Unresolved Anomalies (Bugs or Defects)
   In Appendix 16, in the Section entitled Known Anomaly List, you provided a list of the remaining software anomalies. For several of these anomalies, you stated that that recovery may require power cycling i.e. turning the system off and then on. This is a concern. Please provide a more detailed description of these unresolved anomalies (UAs) and the possible adverse clinical effect(s), and then either mitigate these UAs or provide an acceptable explanation as to why these anomalies should remain extant.

3. Cyber and Information security
   You mention network communications as part of this system. There is not a separate Section addressing the CyberSecurity issues. Please review the Management of Cybersecurity Guidance issued 6/14/13 and provide information, as appropriate, on the Cybersecurity aspects of your device.

4. Run-Time Error Detection
   What tools, (such as static analysis tools), if any, do you use to detect run-time errors. For any such tool used, please identify what error types the tool detects, your method and process of applying the tool(s), and a summary report and/or conclusion about the results. Some common run-time errors are:

   - Un-initialized variables
   - Type mismatches
   - Memory leaks
   - Buffer over/under flow
   - Dead and unreachable code
   - Memory/heap corruption

- Unexpected termination
- Non-terminating loops
- Dangerous Functions Cast
- Illegal manipulation of pointers
- Division by zero
- Race conditions

Prior to submitting the additional information, please familiarize yourself with the following software guidance documents:

"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"
(http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089593.pdf)
5/11/05

"Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices"
(http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073779.pdf) (issued 9/9/1999)

"General Principles of Software Validation; Final Guidance for Industry and FDA Staff" (issued 1/11/2002)
(http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM085371.pdf)

"Guidance for Industry. Cybersecurity for Networked Medical Devices Containing Off-The-Shelf (OTS) Software". (issued 1/14/05)
(http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077823.pdf)

"Content of Premarket Submissions for Management of Cybersecurity in Medical Devices - Draft Guidance for Industry and Food and Drug Administration Staff"
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm356186.htm)
(Issued June14, 2013)

You may also want to consider a review of the following consensus standards: IEC 62304:2006 (Medical device software – Software life-cycle processes) and ISO 14971:2000 (Medical devices - Application of risk management to medical devices).

I will place this submission on hold pending your response with the requested information. You will receive a separate written notification. If you have any questions or need additional clarification, please contact me at (301) 796-6401.